



**For immediate release**

**New Investigational Treatment  
for Vision Loss Shows Promise**

*Alcon's Anecortave Acetate Proving Helpful  
for Treating Wet AMD in Phase II/III Trials*

**Anaheim, California – November 17, 2003** – Wet age-related macular degeneration (AMD) destroys central vision and is the leading cause of blindness in people older than 60. Yet for the hundreds of thousands of people with wet AMD who may become unable to see with enough detail to read, drive, watch television and perform other “close-up” activities, **Retaane™** 15 mg (anecortave acetate for depot suspension), an investigational new drug from Alcon, Inc. (NYSE: ACL), may someday provide a means to preserve their vision, based on the results of a recently completed phase II/III trial.

“Wet” or exudative AMD results from the rapid growth of abnormal blood vessels (choroidal neovascularization, or CNV, lesions) under and towards the center, or macula, of the retina, the light-sensitive tissue lining the back of the eye. As the fragile new vessels grow and proliferate, they frequently leak blood and fluid that accumulates under and lifts the macula. The vessel growth and fluid accumulation separate the retina from its anchoring tissue, causing rapid damage and distortion or loss of vision.

After two years of treatment, **Retaane™** 15 mg Depot has shown efficacy in preserving vision, preventing severe vision loss, and inhibiting new blood vessel growth in patients with the most aggressive type of wet AMD, according to research presented today at the American Academy of Ophthalmology (AAO) annual meeting. This type of wet AMD is characterized by the predominance of abnormal blood vessel growths known as classic CNV membrane lesions.

“Given the size of the Baby Boomer population, the occurrence of AMD is likely to increase significantly in the next decade,” said Peter K. Kaiser, M.D., an ophthalmologist who specializes in Retina at the Cole Eye Institute at the Cleveland Clinic Foundation in Ohio and a participating investigator in the Anecortave Acetate Clinical Study Group. “**Retaane™** Depot has the potential to provide safe and effective long-term therapy for people with this disease. Also, because the mechanism of action for anecortave acetate is different than that of other approved or investigational drugs currently in development for wet AMD, it may be possible to use **Retaane™** Depot therapy alone or in combination with one or more of these other therapies,” said Kaiser.

**Retaane™** 15 mg Depot works by slowing or stopping the growth of new blood vessels, which leads to less leakage and less retinal damage. Unlike other investigational approaches to treat AMD, **Retaane™** 15 mg Depot is administered onto the outer surface of the back of the eye using a specially designed, curved, blunt-tipped cannula that does not pierce the eyeball. **Retaane™** 15 mg Depot’s delivery system – called posterior juxtascleral depot – avoids the risk of intraocular infection and retinal detachment, the most common side effects associated with injecting therapeutic agents directly into the eye.

The **Retaane**™ 15 mg (anecortave acetate for depot suspension) delivery system allows diffusion of the drug over a period of months and requires less frequent administration (once every six months) compared to other investigational treatments, which are given as frequently as nine to 12 times a year. In phase II/III clinical trials, no serious or lasting adverse effects from posterior juxtascleral depot administration were observed in any of the participants.

“We believe **Retaane**™ 15 mg Depot’s unique delivery system could significantly change AMD therapy in patients who need long-term treatment,” said Stella Robertson, Ph.D., Alcon’s Vice President of Pharmaceutical Products, Research and Development. “Treatment every six months will make it easier for patients to comply with the therapy regimen and this could improve both the effectiveness of the treatment and the patient’s quality of life.”

### Phase II/III Study Methods and Results

In the phase II/III monotherapy study, 73 percent of all patients with wet AMD treated with **Retaane**™ 15 mg Depot had stable or improved vision after two years based on measures using the logarithm of the minimum angle of resolution (logMAR) test, a standard vision test. This is significantly more than the 47 percent of patients in the placebo group ( $p=0.035$ ). In the subset of patients with the most aggressive type of wet AMD, lesions with a predominance of abnormal blood vessel growths known as classic CNV, 80 percent had stable or improved vision after 24 months of treatment, compared with only 42 percent of patients receiving a placebo ( $p=0.006$ ).

For the study, investigators randomized 128 patients with wet AMD aged 50 or older to receive **Retaane**™ 15 mg Depot, Anecortave Acetate 3 mg suspension, Anecortave Acetate 30 mg suspension or placebo. A total of 76 patients were available for 12-month follow up, and 55 were available for 24-month follow up.

After 24-month follow up, only 6 percent of all patients treated with **Retaane**™ 15 mg Depot had severe vision loss – defined as a loss of six or more lines of vision on the logMAR test – compared to the 23 percent of patients treated with placebo ( $p=0.073$ ). In the subgroup of patients with predominantly classic CNV lesions, none of the patients treated with **Retaane**™ 15 mg Depot had severe vision loss, compared to 23 percent of patients treated with placebo ( $p=0.023$ ).

**Retaane**™ 15mg Depot was superior to placebo at month 24 for long-term suppression of CNV lesion growth expressed as percent change from baseline. A statistically significant ( $p < 0.05$ ) inhibitory effect of **Retaane**™ 15mg Depot compared to placebo on growth of the classic CNV component of the lesion was demonstrated in both the analysis of all treated eyes and in the analysis of eyes with predominantly classic lesions.

All safety data from clinical trials with **Retaane**™ 15mg Depot have been monitored by an Independent Safety Committee that meets twice a year. The committee determined that no clinically relevant safety issues related to the drug itself have been reported.

### New AMD Trials

In August 2003, enrollment of approximately 500 patients was completed for a multi-center Phase III clinical trial comparing **Retaane**™ 15 mg (anecortave acetate for depot suspension) with photodynamic therapy (PDT) using the light-sensitive angiolytic drug verteporfin (VISUDYNE™, a registered trademark of Novartis, AG). This two-year trial includes a scheduled 12-month analysis of clinical data that will be used for regulatory submissions globally.

Two additional studies comparing monotherapy with **Retaane**™ 15 mg Depot to placebo are enrolling patients in Europe and South America. Alcon is also organizing two

additional studies to evaluate the efficacy and safety of **Retaane™** 15 mg Depot in the treatment of patients with dry AMD who are at significant risk of progressing to wet AMD.

### **About Alcon**

Alcon, Inc. is the world's leading eye care company. Alcon, which has been dedicated to the ophthalmic industry for over 50 years, develops, manufactures and markets pharmaceuticals, surgical equipment and devices, contact lens solutions and other vision care products that treat diseases, disorders, and other conditions of the eye.

###

### **Caution Concerning Forward-Looking Statements**

*This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, relating principally to our ability to complete clinical trials for Anecortave Acetate and file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and the expected benefits of Anecortave Acetate in treating exudative age-related macular degeneration (AMD). These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by our forward-looking statements. These statements reflect the views of our management as of the date of this press release with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that might cause future results to differ include, but are not limited to, the following: we may never submit an NDA for Anecortave Acetate to the FDA, or submission and/or approval of the NDA may take longer than we expect; treatments developed by other companies may reach the market sooner or prove to be more effective than Anecortave Acetate; challenges inherent in new product marketing; and government regulation and legislation. You should read this press release with the understanding that our actual future results may be materially different from what we expect. Except to the extent required under the federal securities laws and the rules and regulations promulgated by the Securities and Exchange Commission, we undertake no obligation to publicly update or revise any of these forward-looking statements, whether to reflect new information or future events or circumstances or otherwise.*

### **For information, please contact:**

Doug MacHatton – Alcon Investor Relations  
(800) 400-8599

Mary Dulle – Alcon Public Relations  
(817) 551-8058